December 11, 2021

Bytech(Dongtai) Co., Ltd.
Boyle Wang
Manager
Shanghai Truthful information Technology Co., Ltd.
Room608,No.738,Shangcheng Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K212899
Trade/Device Name: Disposable Vinyl/Nitrile Blend Medical Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: August 30, 2021
Received: September 13, 2021

Dear Boyle Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212899

Device Name
Disposable Vinyl/Nitrile Blend Medical Examination Gloves

Indications for Use *(Describe)*
The Disposable Vinyl/Nitrile Blend Medical Examination Gloves is intended for medical purposes that is worn on the examiners hands to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K212899 510(k) Summary

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1.0 Submitter's Information

Name: Bytech (Dongtai) Co., Ltd.
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Phone Number: +86-18021873188
Contact: Mr. Wang Cheng
Date of Preparation: 2021.08.30

Designated Submission Correspondent

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2.0 Device information

Trade name: Disposable Vinyl/Nitrile Blend Medical Examination Gloves
Common name: Disposable Vinyl/Nitrile Blend Medical Examination Gloves
Classification name: Non-powdered Patient Examination Glove
Model(s): S, M, L, XL

3.0 Classification

Production code: LYZ
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate device information

Manufacturer: Tangshan Hongyun Healthcare Products Co.,Ltd.
Device: Disposable Vinyl Nitrile Synthetic Gloves Powder Free
510(k) number: K211262

5.0 Indication for Use

The Disposable Vinyl/Nitrile Blend Medical Examination Gloves is intended for medical purposes that is worn on the examiners hands to prevent contamination between patient and examiner.

6.0 Device description

The subject device is powder free vinyl patient examination gloves. The subject device is blue. The design of subject device is addressing the standards as ASTM D6124, ASTM D5151, and ASTM D5250. The subject device is non-sterile.

7.0 Summary comparing technological characteristics with predicate device

Table1-General Comparison

Item	Subject device	Predicated device	Comparison
510(k) number	K212899	K211262	/
Product Code	LYZ	LYZ	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	The Disposable Vinyl/Nitrile Blend Medical Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Disposable Vinyl Nitrile Synthetic Gloves Powder Free is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	ambidextrous	ambidextrous	Same
Labeling Information	Single use, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Single use, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Same

Table2 Device Dimensions Comparison

Predicate	Designation	Size	Tolerance

Device(K211262)		S	M	L	XL	
	Length, mm	230	230	230	230	min
	Width, mm	85	95	105	115	±5
	Thickness, mm:					
	Finger	0.05				min
	Palm	0.05				min
Subject Device	Designation	Size				Tolerance
		S	M	L	XL	
	Length, mm	230	230	230	230	min
	Width, mm	85	95	105	115	±5
	Thickness, mm:					
	Finger	0.05				min
	Palm	0.05				min
Remark	Same					

Table3 Performance Comparison

Item			Subject device	Predicated device	Comparison
Colorant			Blue	Blue	SAME
Physical Properties	Before Aging	Tensile Strength	SAME	11MPa, min	SAME
		Ultimate Elongation	SAME	300%min	SAME
	After Aging	Tensile Strength	SAME	11MPa, min	SAME
		Ultimate Elongation	SAME	300%min	SAME
	Comply with ASTM D5250			Comply with ASTM D5250	SAME
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	SAME
Powder Content			0.15-0.18 mg per glove	0.07 mg per glove. Meet the requirements of ASTM D6124	SIMILAR

Analysis: The powder content is different with that of the predicate, but they all meet the requirements of ASTM D5250 ASTM D6124 - 06(2017).

Table4 Safety Comparison

Item		Subject device	Predicated device	Comparison
Material		Vinyl	Vinyl	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO10993-10	SAME

	Sensitization	Under conditions of the study, not a sensitizer.		
	Cytotoxicity	Under the conditions of the study, the device is potentially cytotoxic	Comply with ISO10993-5	SIMILAR
	Systemic toxicity	Under the conditions of the study, the device does not elicit a systemic toxicity response in the model animal.	Complies with ISO 10993-11 Third edition 2017-09	
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

Analysis: The material of subject device are different with that of the predicate device, but biocompatibility test has been performed on subject device and the test result can meet the requirements of ISO 10993 standards.

8.0 Summary of Non-Clinical Performance Testing

The following performance data has been provided to demonstrate that the subject device meets the acceptance criteria in the standard.

Table 5 Summary of Non-Clinical Performance Testing

No.	Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Results
1	ISO 10993-5	Cytotoxicity	Non-cytotoxic	Under conditions of the study, did not show potential toxicity to L-929 cells.
2	ISO 10993-10	Irritation	Non-irritating	Under the conditions of the study, not an irritant. Pass
3	ISO 10993-10	Sensitization	Non-sensitizing	Under conditions of the study, not a sensitizer. Pass
4	ISO 10993-11	Systemic toxicity	Non-Systemic toxic	Under the conditions of the study, the device does not elicit a systemic toxicity response in the model animal. Pass
5	ASTM D6124-06	This standard is designed to determine the amount ofresidual powder (or filter-retained mass) found	powder residue limit of 2.0 mg	0.15mg -0.18 mg /glove

		on medical gloves		
6	ASTM D5151-06(Reapproved2015)	This test method covers the detection of holes in medical gloves.	Samples number: 125 gloves AQL: 2.5 (ISO 2859) Criterion ≤7 gloves for water leakage	no glove water leakage found
7	ASTM D5250	Physical Dimensions Test	Sterility: no need Freedom from holes: pl. Refer to No. 5 in table 5 Dimensions: Length(mm):≥230； Width(mm): S: 85±5; M: 95±5; L: 105±5; XL: 115±5; Thickness (mm): Finger: ≥0.05 Palm: ≥0.05	N.A. Please refer to No. 5 in table 5 **Lot no. 1:** Dimensions: S: width: 83-88 mm Length 231-238 mm (one data 227mm, the number of non-conforming is 1, acceptable) M: width 92-96 mm Length 233-236 mm L: width 102-106 mm Length 246-253 mm XL: width 111-116 mm Length 242-245 mm Thickness: Finger 0.10-0.11 mm Palm 0.07-0.08 mm **Lot no.:2** Dimensions: S: width: 82-85 mm Length 232-235 mm M: width 92-96 mm Length 232-236 mm L: width 103-106 mm Length 243-249 mm XL: width 111-116 mm Length 237-243 mm Thickness: Finger 0.11-0.12 mm Palm 0.07-0.08 mm **Lot no.:3** Dimensions: S: width: 82-87 mm Length 231-239 mm

						M: width 93-96mm Length 230-239 mm L: width 103-107mm Length 243-249 mm XL: width 112-116 mm Length 244-249 mm Thickness: Finger 0.11 mm Palm 0.07-0.08 mm Pass
8	ASTM D412	Physical properties	Before Aging	Tensile Strength	⩾ 11MPa	Lot 1: 12.7-24 MPa Lot 2: 15.1-25.1 MPa Lot 3: 14.5-23.5 MPa Pass
				Ultimate Elongation	⩾ 300%	Lot 1: 300.08-397.467 % Lot 2: 300.547-380.29 % (one data 228.080, the number of non-conforming is 1, acceptable) Lot 3: 303.365-389.716 % Pass
			After Aging	Tensile Strength	⩾ 11MPa	Lot 1: 14.2-22.4 MPa Lot 2: 16.0-23.8 MPa Lot 3: 14.4-23.3 MPa Pass
				Ultimate Elongation	⩾ 300%	Lot 1: 301.276-394.245 % Lot 2: 300.79-399.170 % Lot 3: 307.674-399.758 % Pass

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.